DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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APR 6 2000

Ms.Paula Torrianni
Cardiovascular Group
Baxter Healthcare Corporation
17221 Red Hill Avenue (Irvine)
Post Office Box 11150
Santa Ana, California 92711-1150

Ref: 00P-0497/CP 1

Dear Ms. Torrianni:

This is in response to your Citizen Petition dated January 19, 2000, and a follow-up letter dated February 7, 2000, in which you request an exemption from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables, Part 898 of Title 21 of the Code of Federal Regulations, as it applies to Baxter volumetric catheters with sensing electrodes. The catheter is connected to monitor via an interface cable.

Your petition states that device identified as the Baxter volumetric catheters with sensing electrodes should be exempted from the performance standard for three reasons. First, the device meets two out of the three tests used to confirm compliance with the performance standard. The device does not meet the finger test. Second, the device will only be used in a hospital environment where you believe the risks will be reduced. Third, your firm has not received any reports of electrical injury due to this device within the past seventeen (17) years.

I am denying your request for an exemption. In addition to not meeting the finger test, FDA analysis has shown that the Safelinc shroud does permit insertion of the 2 mm. exposed pin into some power cords. There are a number of compliant lead wire designs that are available to replace exposed 2 mm. pins. In addition, adapters are readily available that can convert interface cables that were originally designed for use with 2 mm. exposed pins. Furthermore, I do not believe the other reasons provided in your petition are sufficient to grant an exemption from the performance standard. While a hospital environment may reduce the risk of electrical shock, this hazard still exists. Although your firm has not received any reports of electrical injury within the past seventeen (17) years, this does not prevent such an injury in the future.

00P-0497

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I trust that this is responsive to your request. If additional information is required, please contact Kent Berthold in our Office of Compliance at (301) 594-4648.

Sincerely yours,

Linda S. Kahan

Linda S. Kahan
Deputy Director for Regulations
and Policy
Center for Devices and
Radiological Health